



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-3844]

Science Advisory Board to the National Center for Toxicological Research Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) announces a forthcoming public advisory committee meeting of the Science Advisory Board (SAB) to the National Center for Toxicological Research (NCTR). The general function of the committee is to provide advice and recommendations to the Agency on research being conducted at the NCTR. At least one portion of the meeting will be closed to the public.

DATES: The meeting will be held on December 4, 2018, from 8:00 a.m. to 5:45 p.m., and on December 5, 2018, from 8:00 a.m. to 11:30 a.m.

ADDRESSES: Heifer Village, 1 World Avenue, Little Rock, AR 72202. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at:

<https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

FOR FURTHER INFORMATION CONTACT: Donna Mendrick, National Center for Toxicological Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 2208, Silver Spring, MD 20993-0002, 301-796-8892; or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the

Federal Register about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice.

Therefore, you should always check the Agency's website at

<https://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate

advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATON:

Agenda: On December 4, 2018, the SAB Chairperson will welcome the participants, and the NCTR Director will provide a center-wide update on scientific initiatives and accomplishments during the past year. The SAB will be presented with an overview of the SAB Subcommittee Site Visit report and a response to this review. There will be updates from the NCTR research divisions and a public comment session.

On December 5, 2018, there will be a statement given by the FDA Chief Scientist. The Center for Biologics and Evaluation and Research, Center for Drug Evaluation and Research, Center for Devices and Radiological Health, Center for Food Safety and Applied Nutrition, and the Center for Tobacco Products will each briefly discuss their center-specific research strategic needs and potential areas of collaboration.

Following an open discussion of all the information presented, the open session of the meeting will close so the SAB members can discuss personnel issues at NCTR at the end of each day.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available at the location of the

advisory committee meeting, and the background material will be posted on FDA's website after the meeting. Background material is available at <https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

Procedure: On December 4, 2018, from 8:00 a.m. to 5:45 p.m., and December 5, 2018, from 8:00 a.m. to 11:30 a.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before November 27, 2018. Oral presentations from the public will be scheduled between approximately 1:15 p.m. and 2:15 p.m. on December 4, 2018. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before November 19, 2018. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by November 19, 2018.

Closed Committee Deliberations: On December 4, 2018, from 5:45 p.m. to 6:00 p.m., and December 5, 2018, from 11:30 a.m. to 12:00 p.m., the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). This portion of the meeting will be closed to permit discussion of information concerning individuals associated with the research programs at NCTR.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Donna Mendrick at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: October 25, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-23742 Filed: 10/30/2018 8:45 am; Publication Date: 10/31/2018]